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IN THE SUPREME COURT OF THE STATE OF WASHINGTON

JULIE ANDERSON, individually and on behalf of the Estate of
DALTON ANDERSON, and DARWIN ANDERSON individually,

Plaintiffs/Petitioners,

vs.

AKZO NOBEL COATINGS, INC.,

Defendants/Respondents.

BRIEF OF AMICUS CURIAE
NATIONAL FIBROMYALGIA ASSOCIATION

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I. IDENTITY AND INTEREST OF AMICUS CURIAE

The National Fibromyalgia Association (NFA) is the largest 501(c)(3) nonprofit organization serving people with fibromyalgia, a chronic pain disorder affecting about 10 million people in the United States. The NFA provides programs dedicated to improving the quality of life for people affected by fibromyalgia, including advocating for their rights. The NFA focuses on patient support and education, awareness outreach, healthcare provider education, patient advocacy and facilitating scientific research. The NFA has an interest in plaintiffs' rights in the civil justice system and proper admission of medical expert causation testimony.

II. INTRODUCTION AND STATEMENT OF THE CASE

With facts detailed in the Appellant's and Respondent's briefs, we provide only the most salient facts. This appeal involves the proper application of the *Frye* doctrine to expert medical causation opinion testimony in civil cases. On the *Frye* motion to exclude the Andersons' medical expert causation testimony, the Superior Court concluded that the brain defect "can be loosely described as neuronal migration defect." CP 784. It acknowledged jurisdictions that apply *Frye* differently to admit scientific evidence in civil cases and criticism of Washington's approach. CP 782-783. Also stated is the standard for admissibility in *State v. Gregory* and *Grant v. Boccia* to review Azko's argument: the Andersons' causation theory, that prenatal exposure to organic solvents *can* cause

these defects, has not achieved general acceptance in the scientific community and little scientific literature supports it. CP 784. Evidence identified in the Order included the basis of the Andersons' two medical doctors' expert opinions: Dr. Sohail Khattak's training, clinical experience (in medicine, pediatrics and pharmacological toxicology, and his fellowship); medical literature; and, case law¹ in which the Florida Supreme Court held that it is generally accepted in the scientific community that exposure to workplace organic solvents causes brain damage in adults. CP 785. The Order indicated that the single JAMA study, in which underlying statistical information was lost, was insufficient for the Court to determine if the results were "significant" and did not demonstrate any general consensus in the scientific community that prenatal exposure causes neuronal brain defects. CP 785-786. The Court did not address whether or not prenatal exposure to organic solvents *can* cause brain and kidney damage, but focused on the evidence whether or not it *did* cause the damage. The Court also considered defense expert's own 2004 study identifying a higher incidence of cognitive and language

¹ The Order refers to: (1) "only one item of medical literature that found an association between prenatal exposure to organic solvents and a child born with a neuronal migration defect. . .," the 1999 epidemiological study published in the Journal of the American Medical Association ("JAMA") entitled *Pregnancy Outcome Following Gestational Exposure to Organic Solvents* in which Dr. Khattak was the first listed author that studied 125 pregnant women exposed to workplace organic solvents, thirteen (10.4%) of which gave birth to babies with major malformations; (2) the 1993 case report article *Correlation of Prenatal Events with the Development of Polymicrogyria* (a brain disorder the Court earlier characterized as neuronal migration defect) that showed variable growth rate deficiencies; (3) four additional medical articles he considered, which involved studies of children whose parents were exposed to organic solvents (*see* Order, at 7 and ft.3); and, (4) *Berry v. CXS Transp.*, 709 So. 2d 552 (Fla. Dist. Ct. App. 1998) regarding experts' reliance on numerous epidemiological studies to support their opinion that organic solvents exposure caused brain damages in adults. CP 787.

problems with prenatal exposure to organic solvents (CP 788). The Order concludes: 1) expert medical opinions were unable to show a general consensus in the medical community that the birth defects exhibited are caused by prenatal exposure to organic solvents and 2) the causation theory was not generally accepted in the scientific community. It held that causation testimony failed *Frye* and was excluded. CP 790-791.

III. ISSUES PRESENTED

1. Whether, pursuant to *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), the trial court in a personal injury action improperly excluded expert testimony that exposure to organic solvents during pregnancy can cause neuronal birth defects looking at the causation conclusion itself rather than the methods used to arrive at the causation conclusion.
2. Whether the Court should abandon applying *Frye* to expert opinion testimony regarding medical causation questions in civil cases.
3. Whether the Court should recognize causation methodologies (three-step epidemiology causation method, extrapolation, or differential diagnosis) meet the *Frye* test or fall outside *Frye* concerns.

IV. SUMMARY OF ARGUMENT

Washington's application of *Frye* to evaluate admissibility of new scientific evidence should be clarified or eliminated when admissibility of disputed medical expert causation opinion testimony is at issue. Unique and criticized contradictions in *Grant v. Boccia*, 133 Wn. App. 176, 137 P.3d 20 (2006), *review denied*, 59 Wn.2d 1014 (2007) and *Ruff v. Dep't of Labor and Indus.*, 107 Wn. App. 289, 28 P.3d 1 (Div. 1 2001) should be overruled. Andersons' experts, qualifying under ER 702 and 703, deduced their causation opinions from reliable evidence that did not involve novel

methods. *Frye* should not have been triggered. The expansion of *Frye*, beyond novel scientific theory or methods underlying causation testimony to the causation conclusion itself, has transformed issues regarding weight of the evidence into unreasonable admissibility thresholds. It intruded into the province of the jury and prevented the Andersons' presentation of medical expert causation conclusions.

The Court can adopt any one of four fair approaches that meet reliability concerns and define widely applicable criteria for admissibility. One is to exempt medical causation expert opinions from *Frye* in favor of allowing their opinions if experts qualify to render them under ER 702 and 703. A second approach, endorsed in two recent King County Superior Court rulings attached (including the Honorable Andrea Darvas), *Peterson v. Dillon* and *LaMonte v. Westerfield* (see discussion *infra* sections C and E), provides sound reasoning that the Court can adopt to clarify burdens under *Frye* as it applies to medical causation testimony in any civil or criminal case: an established epidemiologic three-step methodology for reliably establishing medical causation. A third approach would allow testimony based on differential diagnosis to form a basis of medical causation opinions outside the ambit of *Frye*. A fourth approach would recognize that extrapolation is an approach to medical causation also outside the ambit of *Frye*. Review, reversal and remand of the Order, will avoid pseudoscience and allow juries to hear live testimony under clarified rules that overcome reliability concerns for admissibility of medical

causation opinions in this and virtually all civil cases involving disputed causation.

V. ARGUMENT

A. *Frye* Was Established To Assure Reliable Scientific Evidence Goes To The Jury

Before discussing why the Court should overrule Judge Darvas' in *Anderson*, overrule *Grant v. Boccia*, clarify how to apply *Frye* to medical causation opinions, or find that *Frye* does not apply to medical expert causation testimony from qualified experts, the Court should examine the purpose of the *Frye* doctrine. *Frye* was developed to make sure that opinions based on new scientific methods were sufficiently reliable to present to a jury and address concern that the cloak of science would yield undue weight to evidence that lacked reliability. A *Frye* analysis looks at *general* acceptance in the *relevant* scientific community to further the goal: presenting reliable evidence to the jury and eliminating *pseudoscience from the courtroom*. *State v. Copeland*, 130 Wn.2d 244, 255, 259, 922 P.2d 1304, 1312, 1314 (1996). Reliability does not require absolute certainty. *Id.*

B. After Objection, the *Frye* Doctrine Permits Novel Scientific Evidence to Be Admitted As Long As The Procedures For Developing The Evidence And Theories Underlying The Procedures Are Generally Accepted In The Relevant Scientific Community

1. General *Frye* Principles In Washington

The 1923 *Frye* rule, on the admissibility of the polygraph test, was

articulated to look at the theory underlying the test and whether it could truly detect lies:

Just when a scientific principal or discovery crosses the line between the experimental and demonstrable states is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle of discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Frye v. United States, 293 F. 1013, 1014 (D.C.Cir.1923). The theory underlying the test, not the conclusion, required general acceptance.

To avoid *pseudoscience* in Washington, if a party proposes evidence that the opponent objects to as subject to *Frye*, the opponent carries the burden to show the proposed evidence is either a *novel principle or scientific method*. If the opponent meets that burden, then the burden shifts to the proponent of the evidence to show it is generally accepted in the relevant scientific community. See, e.g. *In Re Thorell*, 149 Wn.2d 724, 754, 72 P.3d 708,724 (2003). Both parties must establish their burdens with a preponderance of the evidence. *State v. Carlson*, 80 Wn. App. 116, 125, 906 P.2d 999, 1003-1004 (Div.2 1995).²

² As a preliminary question, the *Frye* evaluation falls under ER 104(a). Washington has adopted Evidence Rule 104(a) from the Federal Rules of Evidence, as noted in Section (a) to Comment 104 of the Washington State Rules of Evidence (2005). The United States Supreme Court has established that issues under ER 104(a) should be established to a preponderance. *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579,592 n. 10, 113 S. Ct. 2786, 2796-2797 (1993); *Bourjaily v. United States*, 483 U.S. 171, 175-176, 107 S.Ct 2775, 2778-2779 (1987). See also, *State v. Kunze*, 97 Wn. App. 832, 853, 988 P.2d 977, 990 (1999).

The semantics of “novel principle” has led courts to place medical causation testimony under the ambit of *Frye*. The Court must not look at the conclusions offered, but at the reliability of methods or information relied on to reach a conclusion. *See* discussion *infra* section B(2). The analysis of novelty should focus on the methods the expert uses to arrive at the conclusion, rather than the conclusion itself.³ If *Frye* applies, the proponent of the evidence must prove general acceptance in the relevant scientific community, *i.e.* two different elements of proof: 1) the relevant scientific community, and 2) general acceptance in that community. *See, e.g., In Re Thorell*, 149 Wn.2d 724, 754, 72 P.3d 708, 724 (2003). No Washington appellate case defines the relevant scientific community. However, logically it should be the community with the most understanding of the scientific principles or methods. You do not ask foot doctors about brain surgery. The proponent of the evidence does not need to show unanimity. *State v. Copeland*, 130 Wn.2d 244, 255, 922 P.2d 1304, 1312 (1996). “We are aware that unanimity does not exist. However, we have not held that unanimity among scientists is required before we will find general acceptance in the relevant community.” *Id.* at 270. There

³ *See, e.g., Kaeck v. Lewis County PUD*, 106 Wn. App. 260, 272-277, 23 P.3d 529, 537 (2001) (court can look to a number of sources to see whether new scientific theory meets *Frye*, thus theory that leaking insulator could cause stray voltage on a dairy farm was based on established theories of electricity and any disagreement went to the “weight of the testimony, not the theory”); *State v. Roberts*, 142 Wn.2d 471, 520-522, 14 P.3d 713, 740-741 (2000) (*Frye* not implicated by blood splatter testimony as not novel); *State v. Russell*, 125 Wn.2d 24, 40-41, 882 P.2d 747, 761-762 (1994), cert. denied, 514 U.S. 1129 (1995); *Reese v. Stroh*, 128 Wn.2d 300, 306-307, 907 P.2d 282, 285 (1995) (aff’g that *Frye* test does not apply in civil cases); *Ruff v. Dep’t of Labor and Indus.*, 107 Wn. App. 289, 300, 28 P.3d 1, 7 (Div. 1 2001) (methodology diagnosing porphyria and the causal theory, that chemical exposure caused the porphyria, failed the *Frye* test).

will always be room for a dispute among qualified experts, but a dispute does not automatically mean evidence is not generally accepted, unless the court finds a “*significant* dispute among *qualified* scientists in the relevant scientific community.” *State v. Gore*, 143 Wn.2d 288, 302, 21 P.3d 262, 271 (2001)(*Frye* hearing not necessary on admissibility of DNA typing techniques despite challenges to the statistical methods and the product rule method that were unresolved). Courts have not defined when a dispute becomes a “significant” dispute, although medical causation is typically disputed in personal injury, medical malpractice, or product liability cases. Furthermore, where courts apply *Frye*, they rarely specify the relevant scientific community in which to look for general acceptance, and have not defined how to identify that community or how to assess “general acceptance.”

Based on the burden of proof by a preponderance, it makes sense to require the proponent of the evidence to simply show it is more likely than not that the relevant scientific community accepts the evidence. If the proponent overcomes the *Frye* objection, then with respect to expert testimony, the experts must satisfy ER 702 and 703. In this appeal, there is no serious ER 702 or 703 challenge, so initial issues relate to determining the reliability of the evidence under *Frye* or whether to apply *Frye* at all.

2. The *Frye* Rule Applies To Methodologies for Arriving at Causation Opinions, Not The Causation Conclusions

A causation opinion is a conclusion arising from applying a methodology to facts to deduce the conclusion. As discussed, overcoming

a *Frye* objection to admission of evidence deemed novel, requires the proponent to produce evidence that the expert's methodologies leading to the expert's conclusion are sufficiently established to have gained general acceptance in the relevant scientific community. The Court must look only at expert methodologies, not conclusions based on the methodologies.⁴

State v. Gregory, 158 Wn.2d 759, 829, 147 P.3d 1201, 1238 (2006) notes that once the methodology has been accepted, all challenges go to weight and admissibility under ER 702. The court refers to having made the determination that genetic frequency calculations can be made from an adequate DNA database. The DNA testing is not the conclusion, but the method to look at DNA evidence and determine what it tells us. The discussion of the theory underlying the evidence, in the context of DNA evidence, is very different than talking about medical causation theories.

Two important earlier cases held that the requirement, that expert medical testimony be based on methods generally accepted in the scientific community, pertains to the *methods* used by the experts, not their conclusions. See *Intalco Aluminum Corp. v. Dep't of Labor & Indus.*, 66 Wn. App. 644, 660-661, 833 P.2d 390, 400 (1992) (physicians'

⁴ See, e.g., *State v. Gregory*, 158 Wn.2d 759, 829, 147 P.3d 1201, 1238 (2006); *In Re Thorell et al*, 149 Wn.2d 724,754-755, 72 P.3d 708,724 (2003); *State v. Riker*, 123 Wn.2d 351, 359-360, 869 P.2d 43, 47-48 (1994); *In re Young*, 122 Wn.2d 1, 56-57, 857 P.2d 989 (1993), *cert. denied*, 541 U.S. 990 (2004); *State v. Cauthron*, 120 Wn.2d 879, 889, 846 P.2d 502, 507 (1993); *In Re George Taylor*, 132 Wn. App. 827, 836, 134 P.3d 254, 259 (2006); *Bruns v. PACCAR*, 77 Wn. App. 201, 215-216, 890 P.2d 469, 477-478 (1995), *review denied*, 126 Wn.2d 1025 (1995); *Intalco Aluminum Corp. v. Dep't of Labor and Indus.*, 66 Wn. App. 644, 660-661, 833 P.2d 390, 400 (Div. 1, 1992).

reliance on animal studies for conclusion that toxic exposure more probably than not caused the disease was permissible and they need not "pinpoint" specific toxins as a basis for their conclusions.). It agreed with *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), cert. denied, 469 U.S. 1062 (1984) involving toxic chemical exposure alleged to cause decedent's pulmonary fibrosis. Expert testimony was admitted when it offered a new causal link based only on treating physicians observations, medical tests and studies, which they believed suggested dermal absorption of a toxic herbicide without studies or medical evidence to suggest a causal link between the injury and toxic chemical. The *Intalco* Court said:

We agree with the *Ferebee* court that the requirement that expert medical testimony be based on methods generally accepted in the scientific community pertains to the *methods* used by, not the conclusions of, the expert witness. See also *ER 703*; *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 914-15 (5th Cir. 1987) (an expert physician's opinion on causation need not be generally accepted in the scientific community; it is the *methods* upon which the expert relies in forming his or her opinion that must be generally accepted), cert. denied, 485 U.S. 1009 (1988).

As in *Ferebee*, the techniques and methodologies used by the attending physicians in this case are not challenged. Nor could they be successfully attacked. Drs. Longstreth and Rosenstock did extensive neurologic testing on these patients over a 2-year period. In systematically ruling out all other non-work-related possible causes for the patients' conditions, the physicians used only methods and techniques that are generally accepted in the scientific community. Further, their ultimate conclusion was completely consistent with the toxin-induced model of neurologic disease. In addition, Intalco had the opportunity to, and did, present its own expert medical testimony to challenge the theories on which the attending physicians based their conclusion. That a physician presented a controversial theory possibly linking aluminum exposure to the workers' disabilities did not render the testimony

inadmissible. As in *Ferebee*, this was “a classic battle of the experts, a battle in which the jury must decide the victor.” *Ferebee*, 736 F.2d at 1535.

Intalco Aluminum, 66 Wn. App. at 662 (*emphasis added*).⁵

With respect to medical causation theories, prior to the opinions of Superior Court Judges Andrea Darvas and Richard McDermott attached, Washington courts never specifically addressed the methodologies to determine medical causation presented here. In *Ruff v. Dep’t of Labor & Indus.*, 107 Wn. App. 289, 28 P.3d 1 (2001), Division 1 had all elements of *Frye* from Plaintiff’s experts, who testified that the Mayo clinic test for diagnosing Porphyria was novel and not generally accepted. The court did not perform a serious analysis to exclude the causation testimony because, without being able to diagnose Porphyria and present it to the jury, the Plaintiff’s experts certainly could not testify that Porphyria was caused by the exposure to the toxins. *Id.* at 295-30. However, in distinguishing *Reese v. Stroh*, 128 Wn.2d 300, 907 P.2d 282 (1995), the *Ruff* Court stated that statistical studies are **not** necessary to support a causation opinion (contrary to what Akzo and Judge Darvas focused on in this case), and the reason that the *Reese* Court approved Dr. Fallat’s testimony (about the failure to give Prolastin therapy) is because Prolastin’s use for treating the condition was approved by the FDA. However, there was no study on

⁵ See also, *Bruns v. PACCAR*, 77 Wn. App. 201, 215-216, 890 P.2d 469, 477-478 (1995), *review denied*, 126 Wn.2d 1025 (1995), reiterating that *Frye* addresses novel scientific methodology, not medical opinion based on established scientific technique and, while studies strengthen an expert’s testimony on causation, the competence of expert testimony does not depend on the existence of such studies. *Frye* was found inapplicable to expert testimony that low levels of chemicals in new trucks could produce low level sensory irritation by drivers, because experts relied on established scientific methods of air sampling, chemical analysis, clinical exam, and questionnaires. *Id.* at 215-216.

how likely Prolastin therapy would prevent death – no efficacy data. *Id.* at 303 n.1. Simply because the use of the drug was approved for treatment, Dr. Fallat could testify about its likely effects. The expert was permitted to testify to its likely efficacy *based exclusively on his clinical experience*.

Similarly, causation methodologies discussed below rest on generally accepted methodologies based on basic epidemiologic theory appropriate for causation questions in this case and a broader range of medical causation issues in personal injury, medical malpractice and product liability cases. If the methodology is reliable, the conclusions it produces will be reliable. No Washington appellate court has considered whether a specific epidemiologic method can be sufficient under *Frye* to permit an expert to testify about causation.

3. *Grant* Found Plaintiff Had Not Presented Evidence That The Methodologies to Prove Causation Were Generally Accepted And The Court Did Not Identify The Scientific Community

The *Grant* Court noted a key shortcoming in Plaintiff's evidence:

Although the core concern of *Frye* is only whether the evidence being offered is based on established scientific methodology, the analysis requires both an accepted theory and a valid technique to implement that theory. *Cauthron*, 120 Wn.2d at 889. . . .

Here, the Grants provided no evidence their experts' methodologies to conclude trauma causes fibromyalgia were sufficiently established to have gained general acceptance. Indeed, the record reflects medical science is still unclear as to the processes that trigger fibromyalgia. The simple assertion that their experts' methodologies are common and well-accepted to prove causation does not take their opinions outside the ambit of *Frye*. The "use of a general methodology cannot vindicate a conclusion for which there is no underlying medical

support.” *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999).

Grant v. Boccia, 133 Wn. App. 176, 179-180, 137 P.3d 20 (2006), *review denied*, 159 Wn.2d 1014 (2007)(*emphasis added*). Despite evidence submitted, the Court found Plaintiff did not demonstrate “*the thing from which the deduction can be made was generally accepted in the particular field in which it belongs.*” Plaintiff proposed looking at the foundation for the opinions including clinical experience, case reports, epidemiologic studies, and articles in the general medical literature. Yet, the Court found no evidence of a generally accepted methodology for proving medical causation--only a listing of evidence typically relied on by experts to support a causation opinion. Not addressed was whether epidemiologic methods to determine causation can be a basis for causation testimony.

C. *Frye* Should Not Be Applied to Medical Causation Testimony

Washington’s application of *Frye* has become distorted from its purpose of determining new scientific method reliability. The morphed *Frye* scrutiny, into an added test of general acceptance of medical expert conclusions, should be eliminated leaving only novel scientific methods subject to general acceptance in the relevant scientific community.⁶ Medical opinions should remain tested under ER 702 and 703 to assure reliability.

⁶ *Frye* does not require absolute certainty for sufficiency to present a new method or theory it to a jury. General acceptance in the relevant scientific community keeps *pseudoscience out of the courtroom*. *State v. Copeland*, 130 Wn.2d 244, 255, 259, 922 P.2d 1304, 1312, 1314 (1996).

California's approach would return appropriate admissibility criteria. Judge Darvas' Order pointed out that California does not apply the *Frye* rule to expert medical testimony when it is based entirely upon generally accepted diagnostics methods and tests, "including statistical studies that are not definitive." CP 781. *Roberti v. Andy's Termite & Pest Control, Inc.*, 113 Cal. App. 4th 893, 902 (2003). See *People v. MacDonald*, 37 Cal.3d 351, 373 (1984). Other jurisdictions she cites admit medical causation evidence over a *Frye* objection. CP 781-783.

Illinois permitted **extrapolation** to evaluate the admissibility of disputed causation evidence. *Donaldson v. Cent. Illinois Pub. Serv. Co., et. al.*, 767 N.E.2d 314, 324 (2002):

The medical community may entertain diverse opinions regarding causal relationships, but this diversity of opinion does not preclude the admission of testimony that a causal relationship exists if the expert used generally accepted methodology to develop the conclusion. "In determining whether a novel scientific procedure is 'generally accepted' in the scientific community, the issue is consensus versus controversy over a particular technique * * * Moreover, the mere existence of a dispute does not preclude a finding that the procedure is generally accepted." . . . Simply stated, general acceptance does not require that the methodology be accepted by unanimity, consensus, or even majority of experts. A technique, however, is not "generally accepted" if it is experimental or of dubious validity.

Id. at 324. This clearly excludes "pseudoscience."

D. Epidemiology Provides A Generally Accepted Methodology To Determine Medical Causation In Each Case Applying A Three-Step Process 1) Biologic Plausibility; 2) Temporal Association; And, 3) No More Likely Alternative Explanation

The *Black v. Food Lion, Inc.* opinion (a *Daubert* opinion) cited in *Grant* says “use of a general methodology cannot vindicate a conclusion for which there is no underlying medical support.” *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999). Importantly, footnote 3 in *Black* notes that the plaintiff’s counsel failed to present any studies, supporting literature, or experts on a timely basis so the court never had good evidence to consider. The epidemiologic method for determining causation is a specific methodology that requires underlying medical support, which resolves *Grant*’s concern, and has been accepted recently by two trial courts following several day *Frye* hearings with live expert testimony. Testimony from Injury Epidemiologist, Dr. Michael Freeman, and other experts testifying live in the *Frye* hearings conducted by Judge Darvas in the *Peterson v. Dillon* case and Judge McDermott in the *LaMonte v. Westerfield* case, established that the method is very basic injury epidemiology, reliable for assessing medical causation questions in any individual case. See *App., Ex. C, Hearing Transcripts*. The approach overcomes concern that the first person to suffer a particular injury will not be able to bring a case until science catches up. *Intalco Aluminum Corp. v. Dep’t of Labor & Indus.*, 66 Wn. App. 644, 660-662, 833 P.2d 390, 400 (1992). Individual causation opinions can be reached reliably based on this sound, accepted, and reliable epidemiologic reasoning.

The epidemiologic method involves three steps. First, biologic plausibility requires showing the causation theory that A *can* cause B must

be more than an association. An example of an association cited by Dr. Michael Freeman is the association between a rooster crowing and the sun coming up; an association but no plausible connection between the rooster crowing and the sun coming up. By requiring biologic plausibility, the epidemiologic method removes the evaluation from criticism in *Grant* and provides the scientific basis for the causation conclusion. The second step of temporality is what Defendants often argue taken alone cannot justify a causation opinion citing *post hoc ergo propter hoc* arguments. In epidemiology, temporal association alone is not enough. Yet combined with biologic plausibility and lack of alternate explanations (the third step), it is part of a reliable method to arrive at a causation opinion. That third step strengthens a causation conclusion, making it epidemiologically reliable: for acceptance there must not be any more likely alternative explanation for the medical condition. This is tantamount to making a differential diagnosis, an approach accepted as sufficiently reliable in and of itself to admit evidence in many jurisdictions. See e.g. *Marsh v. Valyou*, 997 So.2d 543 (2007), *rehearing denied*, 2008 Fla. LEXIS 235; *Reichert v. Phipps*, 84 P.3d 353, 357 (Wy. 2004).

In reality, *Frye* should not even apply to this methodology because it is well established, not novel. However, to apply *Frye*, the relevant scientific community is the community of injury epidemiologists who focus on medical causation questions and have developed and accepted

this methodology. *Intalco Aluminum Corp. v Dep't of Labor & Indus.*, 66 Wn. App. 644, 660-662, 833 P.2d 390, 400 (1992).

The Three Step Epidemiologic method allows reliable individual causation opinion to be established by meeting requirements of the three steps using accepted reasoning. The 2009 cases before Judge Darvas in *Peterson v. Dillon* and Judge Mc Dermott in *LaMonte v. Westerfield* overcame *Frye* objection with epidemiologic methods. Experts established that *causation methodologies* that are not novel allow the court to *reliably* admit causation evidence. *Peterson* involved a motion to exclude testimony that trauma led to fibromyalgia and hypermobile joint syndrome, two chronic pain syndromes. Testimony from Epidemiologist Dr. Michael Freeman and other experts demonstrated that the method is very basic injury epidemiology and reliable to assess causation questions in an individual case. *LaMonte* involved revisitation of an adverse ruling prohibiting expert testimony on causation of fibromyalgia with a live expert hearing. As in *Peterson*, taking live testimony better explored this issue.⁷ Defendants raised similar arguments as ones against the Andersons. (See orders *infra*, App., Ex. A *Peterson* and Ex. B *LaMonte*.) While *Grant v. Boccia* led the Anderson Court to focus on the causation conclusion and consider statistical scientific studies (CP 783), subsequently *Peterson* and

⁷ For example: what methodologies the experts use to arrive at conclusions about medical causation; whether the methods are used in contexts other than evaluation of causation of the condition; whether the methodologies implicate, meet *Frye* or appear novel; the relevant scientific community to look for general acceptance. Essentially *Frye*-type inquiry.

LaMonte did not follow *Grant*. They show that expert testimony admissibility under *Frye* does not rely upon statistical scientific studies, but upon general acceptance of the methods to determine causation in the relevant scientific community. This is consistent with precedent. See *Reese v. Stroh*, 128 Wn.2d 300, 306-307, 907 P.2d 282, 285 (1995) (rejecting objection to expert's causation opinion for lack of statistically significant studies proving the drug's efficacy due to FDA approved use). Judge McDermott reasoned that causal relationship studies with objective data requiring long term prospective studies "of such magnitude . . . would be virtually impossible and far too costly to carry out." (Appendix, Ex. B *LaMonte* Order at 4.) Plaintiffs should not have to wait for objective studies before admitting causation testimony.⁸ With generally accepted methodologies, causation testimony has reliable, scientific foundation and is not "pseudoscience."

E. Still Other Generally Accepted Methodologies For Establishing Medical Causation Should Overcome *Frye* Objections Allowing Causation Conclusions, Based On These Accepted Methodologies To Go To The Jury.

This Court should adopt further approaches to satisfy *Frye* concerns. Other generally accepted methodologies overcome reliability worries so causation conclusions can go to the jury. The Florida Supreme Court and other jurisdictions recognize this. In *Marsh v. Valyou*, 977 So.2d 543

⁸ Even statistical analysis of small sample sizes in actuarial models were held to be sufficiently accurate and reliable in satisfaction of ER 702 so that expert testimony based on actuarial instruments to predict future dangerousness was admissible. It had also already been admitted in another case. In *Re Young*, 122 Wn.2d 1, 56, 857 P.2d 989 (1993), *cert. denied*, 541 U.S. 990 (2004).

(2007), the court stated “We conclude that *Frye* does not apply to expert testimony causally linking trauma to fibromyalgia and that, even if it did, such testimony satisfies it.” *Marsh at 545, 550*. It quashed the Florida court of appeals opinion that *Grant* relied on and quoted at 184. *Marsh, id.* at 545. Reviewing medical history, clinical physical examination, doctors own experience, published research and differential diagnosis constituted an accepted methodology for an expert to arrive at a causation opinion. *Marsh, id.* at 548.⁹

Still another approach permits expert medical causation opinions based on clinical experience from evaluating thousands of patients, bolstered by epidemiologic studies, case reports, and writings in general medical literature, patient examination, and review of patient medical records. Combined this is foundation for an epidemiologic approach known as Extrapolation or Analogy. “In the case of scientific study, extrapolation involves establishing a cause and effect relationship based on similar, yet not identical, scientific studies and theories.” *Donaldson v. Cent. Illinois Pub. Serv. Co. et. al.*, 767 N.E.2d 314, 326 n. 2 (2002).

[E]xtrapolation is utilized in the scientific community when the medical inquiry is new or the opportunities to examine a specific cause and effect relationship are limited. . . .

. . .

In some cases, medical science is simply unable to establish the cause and origin of disease. In others medical science does not seek to establish the existence of a cause and effect relationship – for example in this instance, the small

⁹ Interestingly, this description of differential diagnosis, a basis to admit causation testimony on its own, is the last step in the three step epidemiologic method described above looking to eliminate alternate causes.

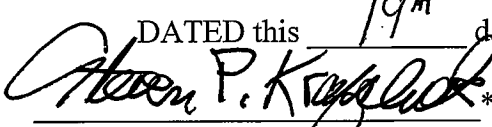
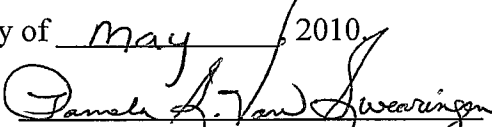
number of neuroblastoma cases limits study of the disease. As a result, extrapolation offers those with rare diseases the opportunity to seek a remedy for the wrong they have suffered. Thus, in these limited instances, an expert may rely upon scientific literature discussing similar, yet not identical, cause and effect relationships. The fact that an expert must extrapolate, and is unable to produce specific studies that show the exact cause and effect relationship to support his conclusion, affects the weight of the testimony rather than its admissibility.

Id. at 328-329.

Washington appellate courts have yet to address if the three step method, differential diagnosis, extrapolation, or any other methodologies can escape *Frye* objection or are generally accepted for medical causation questions. No reason exists to deprive Washington plaintiffs of similar access to the courts when these methodologies are reliable in other jurisdictions.

VI. CONCLUSION

Washington's application of the *Frye* doctrine warrants revision, rather than finding that until medical science determines with sufficient reliability and acceptance that a causal relationship exists, such evidence is inadmissible. If a methodology or epidemiologic approach is adopted for medical causation testimony or if such testimony is exempt from *Frye*, *Frye's* reliability concern will be met with focus on underlying scientific methodologies and the province of the jury will be protected.

DATED this 19th day of May 2010.
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STEVEN P. KRAFCHICK PAMELA S. VAN SWEARINGEN

*Signed original retained by counsel; document transmitted for filing by email.